DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

P940019

Memorandum

Date . MAY 28 1996

From Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of Schneider (USA), Incorporated
WALLSTENT® Iliac Endoprosthesis

To The Director, CDRH
ORA _____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

(1) a premarket approval order for the above referenced medical device (Tab B); and

(2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.

Susan Alpert, Ph.D., M.D.

Attachments
Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved _____ Disapproved _____ Date _____

Prepared by JDANIELSON/swf, CDRH, HFZ-450 443-8243

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

[DOCKET NO. _____]

SCHNEIDER (USA), INC,; PREMARKET APPROVAL OF WALLSTENT®

ILIAC ENDOPROSTHESIS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Schneider (USA), Inc., Minneapolis, MN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the WALLSTENT® Iliac Endoprosthesis. After reviewing the recommendation of the Circulatory System Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter on May 28, 1996, of the approval of the application. In addition, the WALLSTENT® Iliac Endoprosthesis requires tracking under section 519(e) of the act as amended by the Safe Medical Devices Act of 1990.

DATES: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for

administrative review, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

REGISTER).

FOR FURTHER INFORMATION CONTACT:

Judy Danielson,

Center for Devices and Radiological Health (HFZ-450),

Food and Drug Administration,

9200 Corporate Blvd.,

Rockville, MD 20850,

301-443-8243.

SUPPLEMENTARY INFORMATION: On June 9, 1994, Schneider (USA), Inc., Minneapolis, MN 55442, submitted to CDRH an application for premarket approval of the WALLSTENT® Iliac Endoprosthesis. The device is a peripheral stent and is indicated for use following suboptimal percutaneous transluminal angioplasty (PTA) of common and/or external iliac artery stenotic lesions, which are less than or equal to 10 centimeters in length. A suboptimal PTA is defined as a technically successful dilation, judged by the physician to be suboptimal due to the presence of unfavorable lesion morphology such as:

an inadequate angiographic and/or hemodynamic result as defined by a 30 percent or greater residual stenosis after PTA, lesion recoil, or intimal flaps; flow limiting dissections post PTA longer than the initial lesion length; or a 5 mmHg or greater mean transtenotic pressure gradient post PTA.

On March 4, 1996, the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application.

On May 28, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Under section 519(e) of the act as amended by the Safe Medical Devices Act of 1990, manufacturers of certain types of devices are required to adopt a method of tracking that

follows the devices through the distribution chain and then identifies and follows the patients who receive them. FDA has identified the above device as a new generic type of device requiring tracking. FDA is providing a 30-day period for interested persons to submit to the Dockets Management Branch (address above) written comments regarding the agency's position that this new generic type of device requires tracking.

Opportunity For Administrative Review

Section 515(d)(3) of the act, (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through

administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated:_____.

_____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 1996

Ms. Amy Peterson
Director of Regulatory Affairs
and Biological Services
Schneider (USA), Incorporated
Pfizer Hospital Products Group
5905 Nathan Lane
Minneapolis, Minnesota 55442

Re: P940019
WALLSTENT® Iliac Endoprosthesis
Filed: June 9, 1994
Amended: September 26, 1994, June 29, July 28 and December 26 1995, January 17 and 30, February 7 and 8, April 4 and 17, May 6 and 15, 1996

Dear Ms. Peterson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the 6 mm through 10 mm diameter WALLSTENT® Iliac Endoprosthesis. This device is indicated for use following suboptimal percutaneous transluminal angioplasty (PTA) of common and/or external iliac artery stenotic lesions, which are less than or equal to 10 cm in length. A suboptimal PTA is defined as a technically successful dilation, judged by the physician to be suboptimal due to the presence of unfavorable lesion morphology such as:

an inadequate angiographic and/or hemodynamic result as defined by a 30 percent or greater residual stenosis after PTA, lesion recoil, or intimal flaps;

flow limiting dissections post PTA longer than the initial lesion length; or

a 5 mmHg or greater mean transtenotic pressure gradient post PTA.

We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502 (q) and (r) of the act.

Expiration dating for this device has been established and approved at two years. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(8).

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that as soon as possible, and before commercial distribution of your device, that you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

Our approvable letter of May 7, 1996, stated that under section 522(a)(1)(A) of the act, your device required postmarket surveillance. Please be advised that this was not correct; peripheral stents are not listed as devices requiring such surveillance. Therefore, you will not be required to submit a protocol which describes a postmarket surveillance study.

Under section 519(e) of the act (as amended by the Safe Medical Devices Act in 1990), manufacturers of certain devices must track their products to the final user or patient so that devices can be located quickly if serious problems are occurring with the products. The tracking requirements apply to (1) permanent implants the failure of which would be reasonably likely to have serious adverse health consequences; (2) life sustaining or life supporting devices that are used outside of device user facilities the failure of which would be reasonably likely to have serious adverse health consequences; and (3) other devices that FDA has designated as requiring tracking. Under section 519(e), FDA believes that your device is a device that is subject to tracking because it is a permanent implant whose failure would be reasonably likely to have serious adverse consequences

FDA's tracking regulations, published in the FEDERAL REGISTER on August 16, 1993, appear at 21 CFR Part 821. These regulations set out what you must do to track a device. In addition, the regulations list example permanent implant and life sustaining or life supporting devices that FDA believes must be tracked at 21 CFR § 821.20(b) and the devices that FDA has designated for tracking at 21 CFR § 821.20(c). FDA's rationale for identifying these devices is set out in the FEDERAL REGISTER (57 FR 10705-10709 (March 27, 1991), 57 FR 22973-22975 (May 29, 1992), and 58 FR 43451-43455 (August 16, 1993)). Pursuant to 21 CFR § 821.20(d), FDA will be adding peripheral stents/class III to these lists by publishing a notice in the FEDERAL REGISTER announcing that FDA believes that this device is subject to tracking under section 519(e)(1). This notice will also solicit public comments on FDA's determination.

If you have questions concerning this approval order, please contact Judy Danielson at (301) 443-8243.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mixup of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

(1) may have caused or contributed to a death or serious injury or

(2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, Room 240
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

SUMMARY OF SAFTETY AND EFFECTIVENESS

I. General Information

Device Generic Name:	Intravascular Stent
Device Trade Name:	WALLSTENT® Iliac Endoprothesis with Unistep™ Delivery System
Applicants's Name and Address:	Schneider (USA) Inc. 5905 Nathan Lane North Plymouth, MN 55442
PMA Number	P940019
Date of Notice of Approval to the Applicant:	MAY 28 1996

II. Indications for Use

The Schneider WALLSTENT® Iliac Endoprosthesis is indicated for use following suboptimal percutaneous transluminal angioplasty (PTA) of common and/or external iliac artery stenotic lesions, which are $\leq$ 10 cm in length. A suboptimal PTA is defined as a technically successful dilation, judged by the physician to be suboptimal due to the presence of unfavorable lesion morphology such as :

an inadequate aniographic and/or hemodynamic result as defined by a 30% or greater residual stenosis after PTA, lesion recoil, or intimal flaps;

flow limiting dissections post PTA longer than the initial lesion length; or

a 5 mmHg or greater mean transtenotic pressure gradient post PTA.

III. Device Description

DESCRIPTION
The Schneider WALLSTENT® Iliac Endoprosthesis is comprised of two components: the implantable metallic stent and the 7 Fr Unistep™ delivery system. The stent is composed of biomedical superalloy wire, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant and self-expanding. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during deployment. Radiopaque marker bands situated adjacent to the leading and trailing ends of the stent facilitate imaging during deployment. The interior tube of the coaxial system contains a central lumen which will accommodate a 0.035" or 0.038" guidewire. The device may be inserted through an 8 French introducer.

IV. Contraindications

The WALLSTENT® Iliac Endoprosthesis is contraindicated for use in:

- Patients who exhibit persistent acute intraluminal thrombus at the proposed stenting site, post thrombolytic therapy.
- Patients who experience the complication of arterial perforation, or a fusiform or sacciform aneurysm during the procedure preceding possible stent implantation.

V. Warnings

- Care should be taken during stent deployment to avoid stent placement beyond the iliac ostium into the aorta as this may result in thrombus formation.
- Stents cannot be repositioned or removed after total deployment.

VI. Precautions

- Stenting across a major bifurcation may result in stenosis or occlusion of the non-stented vascular limb, and prevent or hinder future access for angioplasty procedures.
- The device is intended for use by physicians who have received appropriate training in interventional techniques and placement of intravascular stents.
- The WALLSTENT® Iliac Endoprosthesis may cause minimal artifacts in MRI scans due to distortion of the magnetic field.
- The WALLSTENT® Iliac Endoprosthesis is intended for single use only. The sterile packaging and device should be inspected prior to use. If it is suspected that sterility or performance of the device has been compromised, it should not be used.
- The WALLSTENT® Iliac Endoprosthesis should **NOT** be resterilized.
- The safety and effectiveness of the WALLSTENT® Iliac Endoprosthesis for use in total nonthrombotic iliac artery occlusions has not been established.
- The safety and effectiveness of the WALLSTENT® Iliac Endoprosthesis in patients for whom antiplatelet, anticoagulation therapy, or thrombolytic drugs are contraindicated or who exhibit coagulopathy has not been established.
- The safety and effectiveness of the WALLSTENT® Iliac Endoprosthesis for use in pediatric patients has not been established.
- The safety and effectiveness of the WALLSTENT® Iliac Endoprosthesis for use at a lesion site within a vascular graft or at the anastomosis has not been established.

VII. Adverse Events

The clinical study of the WALLSTENT® Iliac Endoprosthesis included 119 patients receiving 165 stents at 13 U.S. centers with a mean duration of 3.3 years and a range of 2 days to 4.3 years.

Fifteen patients died during the study. None of these deaths were believed to be device or procedure related.

The proportion of patients with adverse events (major and minor) reported in the 119 patients are listed below according to clinical importance.

Table 1 - Adverse Events (n=119)*

Event	<30 days	Total
Thrombosis	0%	3.4%
Stent Misplacement	3.6%	3.6%‡
Bleeding Requiring Transfusion	0.8%	0.8%
Hematoma Requiring Repair	0.8%	1.7%†
Distal Emboli	1.7%	1.7%
Pseudoaneurysm	0.8%	0.8%
Minor Hematoma	7.6%	8.4%†
Intraluminal Thrombus (subtotal)	0%	1.7%
Cerebrovascular Incident	0%	1.7%
Death	2.5%	12.6%

* Analysis on 119 of 140 patients in 137 limbs. Twenty-one patients excluded, 10 for not meeting study entry criteria & 11 were total occlusions.
‡ Aortic bifurcation involved 1.8%.
† One event occurred at follow-up angiography.

Additional adverse effects associated with iliac stenting, although not observed in the clinical study include:

- Vessel Rupture
- AV Fistual Formation
- Sepsis/Infection
- Stent Migration

The risks associated with the use of contrast media angiography (allergic type reactions, hypertension, shock, death) should also be considered, as fluoroscopy and angiography are recommended during the stent implant procedure.

VIII. Alternative Practices and Procedures

The WALLSTENT® Iliac Endoprosthesis was evaluated as an adjunctive treatment to failed PTA in the common and external iliac arteries. At the clinical study onset, bypass graft surgery was the only alternative. As of September 1991 an alternate iliac stent became commercially available.

IX. Marketing History

The WALLSTENT®Iliac Endoprothesis is legally marketed in the United States and internationally as the WALLSTENT® (Transjugular Intrahepatic Portosystemic Shunt) TIPS Endoprosthesis, WALLSTENT® Transhepatic

Biliary Endoprosthesis, WALLSTENT® Endoscopic Biliary Endoprosthesis, and the WALLSTENT® Tracheobronchial Endoprosthesis, for the intended use of TIPS, biliary and tracheobronchial stenting.

The WALLSTENT® Iliac Endoprothesis is commercially available in 33 other countries as listed below.

Australia	Denmark	Japan	S. Korea
Austria	Finland	Mexico	Slovak Republic
Belgium	France	Norway	Slovenia
Brazil	Germany	Poland	Spain
Canada	Greece	Portugal	Sweden
Croatia	Hong Kong	Russia	Switzerland
Cyprus	Hungary	Singapore	Taiwan
Czech Republic	Italy	S. Africa	Turkey
			United Kingdom

There are no countries in which the device has been withdrawn from marketing for any reason including those related to safety or effectiveness.

X. Summary of Studies

A. *In Vitro* (Labratory) Studies

1. Biocompatibility of the endoprosthesis and the delivery system were shown to be acceptable by the following tests which were performed in accordance with the Tripartite Biocompatibility Guidance and Good Laboratory Practice Regulations:

Irritation/Intracutaneous Toxcity	Hemolysis
Sensitization	Acute Systemic Toxicity
Pryogenicity	Cytotoxicity
Limulus Ameboxyte Lysate (LAL)	Implantation
Mutugencity	

2. Sterility: The WALLSTENT® Iliac Endoprothesis with Unistep™ Delivery System is sterilized by a validated 2.5 Mrad (25kGy) gamma radiation cycle. The validation method employed was the AAMI Method 3, Guideline for Gamma Radiation Sterilization (ANSI/AAMI ST 32-1991, October 18, 1991). Validation results demonstrated the product when exposed to a minimum dose of 2.5 Mrads had a sterility assurance levels of 10^{-6}.

3. Shelf Life and Shipping Studies: Product stability testing for the WALLSTENT Iliac Endoprosthesis with Unistep Delivery System was performed. This testing indicated that the package components are stable and sterility is maintained for a minimum of 24 months. Based upon these results, an expiration date of 24 months was established.

4. Stent Material Composition Conformance: To determine the composition of the implant-grade cobalt-base super-alloy wire used to construct the stent, the composition was analyzed by the wire manufacturer according to ISO 5832/7 and ASTM 1058-91. Certification demonstrated appropriate chemical composition.

5. Wire Performance: To determine wire conformance to specifications for yield strength and elongation 13 samples per wire diameter (0.0039-0.0055") per test were evaluated and found to meet specifications.

6. Stent Wire Mechanical Properties Conformance: The mechanical properties of the smallest and largest diameter stent wire were assessed following a heat-treating process which imparts additional memory and elasticity to the stent. Results demonstrated compliance to established specifications.

7. Percentage "Free Area": The percentage free area, i.e., area not in contact with the vessel wall, for the smallest and largest diameter stent was determined. Theoretical results demonstrated a percentage free area range of 72.9% to 73.2%.

8. Stent Wire Dimensional Conformance Test: To determine the dimensional consistency of the stent, constrained stent length, wire count, unconstrained stent outer diameter, wire diameter and stent braid angle were measured for 21-26 units of the 6 and 8 thru 10mm diameter stents. Results demonstrated dimensional compliance to established specifications.

9. Radial Force: To determine the radial force exerted by the stent at various diameters, 5 units each of the smallest and largest stents were evaluated and compared to predicted values. Results were found to be statistically within predicted values.

10. Stent Deformation: Thirteen to 21 units of the 6 mm and 8 mm thru 10mm diameter stents were evaluated to determine the effects of repeated external deformation on the stent to simulate compression of a peripheral vessel in an ambulatory patient. Results demonstrated the stent can withstand repeated (20X) external deformation without wire fracture. In addition, there was no significant change in the inner diameter of the stent following this testing.

11. Stent Fatigue: The fatigue characteristics of an implanted stent in a peripheral vessel based on simulated worst case mechanical characteristics was predicted. The finite element analysis (FEA) demonstrated the stent will not fracture during an infinite period of time when implanted in the iliac arteries of adult patients.

The fatigue characteristics are predicted by applying a three step design approach to support the durability of stents. The first design approach was to determine the fatigue strength of the wire by means of a U-bend spin fatigue testing. The U-bend shaped stent wire is rotated 360 degrees generating alternating stress (tension/compression) to its apex. Applied stress levels are varied by changing the radius of the bend. Fatigue data is extrapolated from actual stress versus accumulated cycle results and is statistically analyzed. The analysis identifies stress level that supports a 10 year expected fatigue life.

The second step is to create a Modified Goodman diagram, commonly used to compare variable cyclic-stress conditions. The equivalent stress level for the expected 10 year fatigue life is plotted as the upper boundary condition of the Modified Goodman polygon. Stress levels interior to this boundary on the polygon are expected to not cause fatigue failure.

Thirdly, the FEA determined the stress distribution generated within the stent structure. The FEA procedure, a numerical, modeling technique combines the stresses from fabrication and axial extension into a conservative summation of maximum stresses. The analysis reports the stress of a fully unconstrained stent, at a range to support the labeling, as well as a fully constrained stent on the delivery system. All stent stresses from these conditions fell within the safe stress polygon boundaries indicating the stent is acceptable for use.

12. Corrosion Testing: To estimate the corrosion characteristics of the biomedical super-alloy wire under standard in vivo conditions, testing was performed per ASTM F 746 and G 582 on a sample size of nine stents. The results indicated a very high resistance to pitting and crevice corrosion. Corrosion could not be induced in the metal specimens, even when the critical potential was increased to over 800 mv.

13. Radiopacity Comparison: Testing per ASTM F 640, Method B was conducted on two delivery systems with constained stents. The stent and delivery system marker bands are clearly visible.

14. MRI Field Compatibilty: To estimate the effects of the implanted stent on MRI fields during MRI procedures, published literature was examined which demonstrated that the WALLSTENT® Iliac Endoprosthesis can be imaged without degradation or stent deflection. However, minimal artifacts may result due to distortion of the magnetic field.

15. Delivery System Stent Deployment Force: To demonstrate the force required to deploy a stent under modeled end use conditions and conformance to specification, testing was performed on 30 units. Results demonstrated the natural limits (mean $\pm$ 3SD) were in compliance with specifications.

16. Delivery System Bond Strength: To demonstrate the strength of the bonded joints and their ability to resist failure, testing was performed on 23-30 units per seven different bond sites. Results demonstrated the natural limits for all bonds met and exceeded the established minimum specification.

17. Delivery System Mechanical Dimensions: To demonstrate proper mechanical dimensions of the delivery system, testing was performed on 24 units. Results demonstrated dimensional compliance to established specifications.

B. *In Vivo* (Animal) Studies

Investigations of the WALLSTENT® Iliac Endoprosthesis began in animal models in the early 1980's. Prototype stents were the focus of an intial report by Maass et al, who presented his findings in Europe in 1982 and 1983, and in U.S. in 1984. Other animal investigations were summarized by Duboucher (1986 - unpublished data), Sigwart et all (1987), and Rousseau et all (1987 and 1988). Additional work by Redha (1988 - unpublished data) evaluated the stent's interaction with normal canine iliac arteries implanted with the WALLSTENT® Iliac Endoprosthesis. Together, this preliminary research provided models to evaluate the foreign body and healing responses to the implanted stents.

Animal studies using the WALLSTENT® Iliac Endoprosthesis have provided information regarding the selection of appropriate vessels for stenting, the optimal stent size for the selected vessel and the effect of anticoagulant therapy on the incidence of thrombosis.

The endoprosthesis induces minimal inflammatory change at the implant site. Following implantation, a series of vessel remodeling activities occur that result in reconstruction of the endothelial layer over the stent. During the first four to six weeks of this post-operative process, a gradual thickening of the vessel wall occurs. The wall eventually decreases in thickness, and attains a near normal level approximately six months post-implant.

C. Clinical Studies

The clinical study of the WALLSTENT® Iliac Endoprosthesis was conducted from August 27, 1991 to April 21, 1993, under IDE G910018. The purpose of the study was to evaluate the safety and effectiveness of the device for use as an adjunct to angioplasty for the treatment of peripheral vascular disease in iliac arteries of adult patients with suboptimal PTA result. The study design was that of a prospective, multi-center, non-randomized trial. The patient study group described in the Summary of Safety and Effectiveness of the Palmaz Balloon Expandable Stent, along with an updated published journal article served as the control group.

Clinical Study Definitions:

Acute Procedure Sucess. Limbs with $<50\%$ residual stenosis immediately after stent placement and no major complications within the lab. This will be determined by the film reading at both the investigational site and core lab.

30 Day Procedure Success. Limbs with $<50\%$ residual stenosis immediately after stent placement and no major complications within 30 days of implant.

Early Clinical Success. Limbs with Rutherford/Becker Classification ≥ 1 at the latest follow-up between hospital discharge and early post-treatment follow-up (approximately 42 days).

Angiographic Success. Limbs with $<50\%$ stenosis as assessed at six month follow-up ($\pm$ three months) and at latest follow-up, as determined by angiography.

Late Clinical Success. Maintenance of achieved improvement in the appropriate segmental limb pressure index (ABI or TBI) which if not normalized (<0.90) must have increased by at least 0.10 over the initial preoperative level and not have deteriorated by more than 0.015 from the maximum, early post-procedure level. If ABI or TBI is unavailable or unreliable, symptoms must be improved over baseline (Rutherford/Becker Class ≥1).

Combined Hemodynamic and Clinical Success - Rutherford/Becker Criteria. Since the initiation of the study, standards for reporting results for peripheral vascular disease studies have been published. The Rutherford/Becker Classification was developed as a part of these reporting standards and assesses post operative hemodynamic and clinical improvement. Patient records were reviewed by the principle investigator for the study (Eric Martin, M.D.) and a Rutherford/Becker classification was assigned retrospectively using the following criteria:

+3 = Normalized ABI or TBI >0.90 (Marked improvement)

+2 = Improvement in one clinical category AND increase in ABI by 0.1, but not normalized. (Moderate improvement: categorical improvement but still symptomatic)

+1 = Improvement in one clinical category OR increase in ABI by 0.1 (minimal improvement)

0 = No categorical shift and <0.1 increase in ABI

-1 = No categorical shift and decrease in ABI >0.10 or downward categorical shift and decrease in ABI <0.10

-2 = Downward categorical shift or unexpected minor amputation

-3 = More than one category worse or unexpected major amputation

Primary Patency. Defined as the proportion of patients, over time, that have had uninterrupted (intervention-free) patency since the initial procedure. Primary patency ends at the first occurrence of one of the following: initial reintervention for the purpose of treating patency of the original lesion; total occlusion of the original lesion; or when the stent segment is bypassed or amputation of the extremity occurs due to restenosis or occlusion.

Primary Assisted Patency. Defined as the proportion of patients, over time, that have had an intervention to assist patency maintenance since the initial procedure without an episode of vessel total occlusion. Failure of primary assisted patency occurs at the time of original lesion total occlusion, or when the stented segment is surgically bypassed or amputation of the extremity occurs due to restenosis of occlusion.

Secondary Patency. Defined as the proportion of patients, over time, that have a totally occluded vessel that was successfully opened. Failure of secondary patency occurs at the time the stented segment is surgically bypassed or amputation of the extremity occurs due to restenosis or occlusion.

Early Clinical Events. Clinical events which occurred within 30 days of the stent procedure.

Late Clinical Events. Clinical events which occurred after 30 days from the initial procedure.

Major Complication (clinical events). Includes death, stroke, bleeding requiring transfusion, or any complication which is device or procedure related which requires a surgical procedure or interventional procedure.

Thrombosis. Total occlusion (100% stenosis) of the artery due to the presence of thrombus.

Intraluminal Thrombus. Subtotal occlusion of the artery due to the presence of thrombus.

Delivery System Failure. Delivery system did not perform as intended during stent placement procedure.

Study Inclusion and Exclusion Criteria:

Inclusion Criteria. Patients were considered eligible for study enrollement provided one or more of the following characteristics were demonstrated:

- Supoptimal angioplasty. A technically successful dilatation but judged by the physician to be suboptimal due to the presence of an unfavorable lesion morphology such as:

  - an inadequate angiographic and/or hemodynamic result as defined by a 30% or greater residual stenosis resultant to PTA, lesion recoil, or intimal flaps;

  - flow limiting dissections post PTA longer than the initial lesion length; or

  - a 5 mmHg or greater mean transtenotic pressure gradient post PTA in iliac arteries.

Exclusion Criteria. Patients were excluded from the clinical trial if they met any of the following criteria:

- Poor runoff in the femoral system, the protocol required a patent femoral-popliteal artery with $<50\%$ stenosis, or a well developed profunda collateral system;
- A single or multiple lesions $>$ 10cm;
- Perforation or aneurysm formation at the angioplasty site;
- Lesions within a vascular graft or within 2 cm of the anastomosis;
- Patients in whom antiplatelet, anticoagulants, or thrombolytic drugs were contrandicated;
- Pregnancy;
- Patients with hepatic insufficiency, nephrotic syndrome, thrombophlebitis, uremia or deep vein thrombus, and those patients receiving dialysis, or taking immunosuppressants;
- Patients with other stents or in other protocols;
- Patients who exhibit coagulopathy;
- Patients who exhibit persisting acute intraluminal thrombus at the proposed stenting site, post thrombolytic therapy; and
- Patients incapable of conforming to the clinical study protocol and follow-up requirements or those exposed to additional risks apparent to the physician.

Demographics:

The trial involved 140 patients (163 limbs) at 13 investigational sites in the United States. Twenty-one patients (26 limbs) were excluded from analysis, ten patients because they fell within the exclusion criteria delineated for the study and 11 patients were total occlusions. Therefore, the analysis cohort was comprised of 119 patients (137 limbs). Full patient demographics are presented in Table 1.

Table 1 - Demographics (n=119)*	
Age (Yrs)†	63.5 ± 11.3 (38-85)
Gender	67% Male 33% Female
Current or Recent Smoker	59.7%
SVS (n=121 limbs)†	2.56 ± 1.12 (0-6)
ABI (n=120 limbs)†	0.65 ± 0.17 (0.24-1.09)
NYHA (%)	I-70, II-23, III-7, IV-1
Diabetes	30.3%
Hypertension	57.1%
Hypercholesteremia	41.2%
Hyperlipidemia	26.9%
Myocardial Infarction	33.6%
Angina	29.4%
CHF	8.4%
Stroke	5.9%
TIA	3.4%
COPD	10.9%

* Analysis on 119 of 140 patients. Twenty-one patients excluded, 10 for not meeting study inclusion or exclusion criteria and 11 were total occlusion patients. There were 137 limbs in 119 patients.
† Mean ± SD, (range).

Evaluation of Gender Bias:

To determine whether gender bias had occurred during the clinical study, the ratio of women to men treated with the WALLSTENT® Iliac Endoprosthesis was compared to the gender distribution from the medical literature for PTA (Johnson et al) as well as the Palmaz Summary data. The percent male was 67% in both the PTA literature summary and the WALLSTENT® Iliac Endoprosthesis trial. In the Palmaz summary and update data set the percent male was 75 and 80%, respectively. There was a statistical significant difference between the WALLSTENT® trial compared to the Palmaz summary and update data ($p=0.009$ and $p=0.081$, respectively) meaning a higher portion of females was represented in the WALLSTENT® Iliac Endoprosthesis trial. There was no significant relationship between gender and any efficacy outcome variable (all $p > 0.30$).

Results:

Figure 1 illustrates the distribution of lesion length. Table 2 presents baseline lesion characteristics. An average of 1.2 stents per limb were utilized.

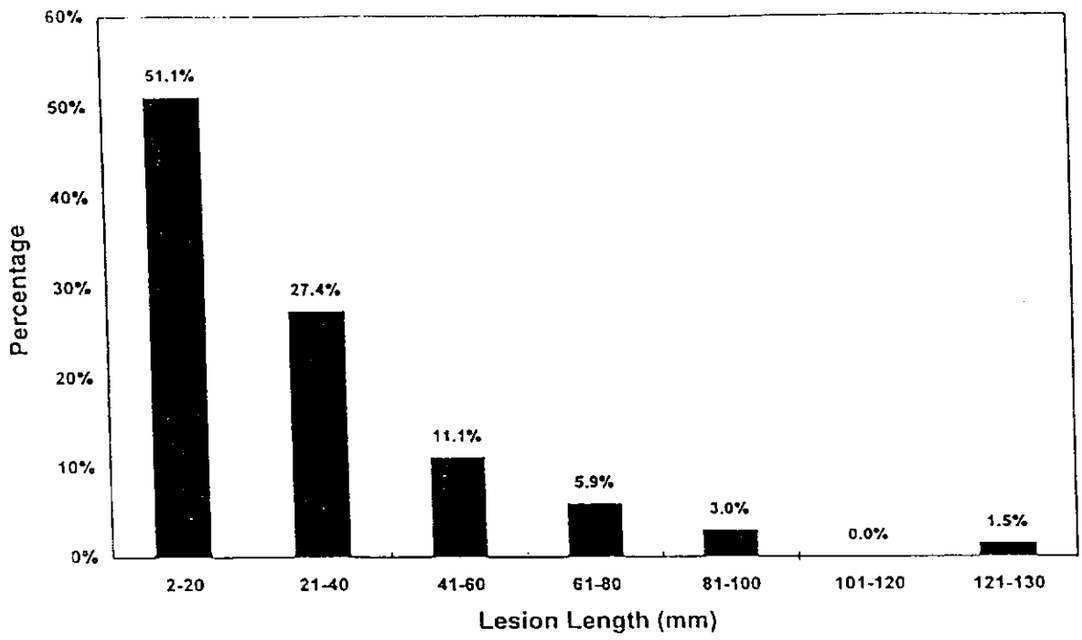

Figure 1. Distribution of Lesion Length as Reported by Investigational Sites

Table 2 - Baseline Lesion Characteristics (Unit of Analysis is Limbs)

		Mean ± SD or %	Range Among Sites
Lesion Length (mm) (n=135 limbs)		30.30 ± 25.04	4.0 - 59.2*
Location of Lesion (n=137 limbs)	Common	48.9%	0 - 100%
	External	51.1%	0 - 100%
Calcification Present (n=134 limbs)	No	45.5%	0 - 80%
	Yes	54.5%	
Eccentric Lesions (n=136 limbs)	No	34.6%	37.5 - 100%
	Yes	65.4%	

* Two patients had lesions > 100mm prePTA but stent length < 100mm and therefore were not excluded.

Procedural characteristics are documented in Table 3 and early success measures in Table 4.

Table 3 - Procedural Characteristics

Variable		Mean ± SD or Number	%
Indication for Stenting (n=137 limbs)	Acute Restenosis[1]	2	1.5
	Angioplasty Failure	103	75.2
	Pressure Gradient Failure	10	7.3
	Angioplasty & Pressure Gradient Failure	22	16.1
Angioplasty Failure Indication (n=125 limbs)	Residual Stenosis	41	32.8
	Flap Stenosis	11	8.8
	Elastic Recoil	2	1.6
	Residual Stenosis & Flap	43	34.4
	Residual Stenosis & Recoil	20	16.0
	Flap & Recoil	1	0.8
	Residual Stenosis, Flap, & Recoil	7	5.6
Hospital Stay (days) (n=119 patients)	Mean	2.2 ± 3.1	-
	Median	1	-
	Range	0-24	-
Balloon Diameter (mm) (n=129 limbs)	Mean	7.7 ± 1.1	-
	Range	5-11	-
Balloon/Artery Ratio (n=129 limbs)	Mean	0.98 ± 0.13	-
	Range	0.71-1.57	-
Stent Size Distribution (mm) (n=165 stents)	6	9	5.5
	7	31	18.8
	8	54	32.7
	9	42	25.4
	10	29	17.6
Average Stents Per Limb (n=137)		1.2	-

[1] Failed angioplasty was ≤ 48 hours prior to stent implant.

Table 4 - Quantitative Angiographic Analysis Reported by Investigational Site (Parentheses Contain the Core Lab Data)					
		Pre-Procedure	**Post-PTA**	**Post-Procedure**	**Six Month Angio FU**
Reference Vessel Diameter (mm)	n	137 (109)	-	-	- (33)
	Mean	8.00 (6.76)	-	-	- (6.55)
	SD	1.37 (2.38)	-	-	- (2.01)
% Stenosis	n	137 (109)	124 (74)	137 (112)	65 (33)
	Mean	69.6 (71.6)	46.8 (35.0)	8.0 (0.3)	12.1 (10.0)
	SD	16.9 (14.9)	21.5 (17.4)	15.1 (20.0)	23.7 (2.1)
% Restenosis (≥50% stenosis)	n	-	-	1/137 (2/112)	6/65 (2/33)
	%	-	-	0.7 (0.9)	9.2 (6.0)
Minimum Lumen Diameter (mm)	n	137 (109)	124 (74)	137 (112)	65 (33)
	Mean	2.46 (1.83)	4.21 (4.43)	7.28 (5.75)	6.84 (5.39)
	SD	1.48 (1.18)	1.70 (1.76)	1.34 (1.97)	1.96 (1.77)
Acute Gain Minimum Lumen Diameter[1] (mm)	n	-	-	65 (25)	-
	Mean	-	-	4.95 (4.85)	-
	SD	-	-	1.69 (2.08)	-
Net Gain Minimum Lumen Diameter[1] (mm)	n	-	-	-	65 (25)
	Mean	-	-	-	4.59 (3.95)
	SD	-	-	-	2.41 (1.82)
Net Loss Minimum Lumen Diameter[1] (mm)	n	-	-	-	65 (25)
	Mean	-	-	-	0.36 (0.90)
	SD	-	-	-	1.76 (2.22)

MLD = Minimum Lumen Diameter
[1] Data presented for patients with pre-procedure, post-procedure, and six month follow-up results.

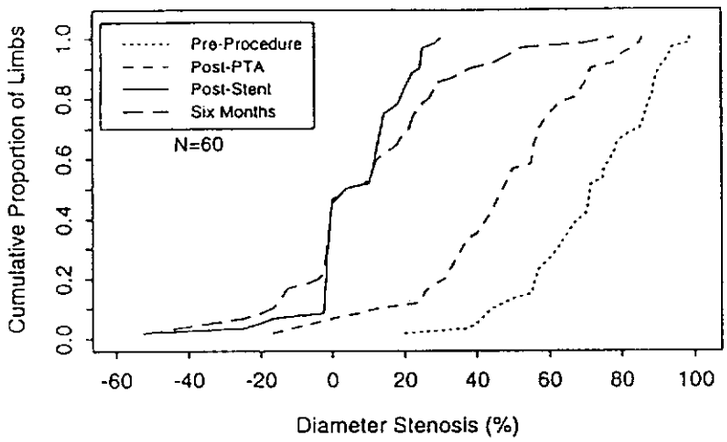

Figure 2. Baseline, Post-PTA, Post-Procedure, and Six Month Angiographic Percent Diameter Stenosis for Limbs with All Four Measurements - Investigational Sites

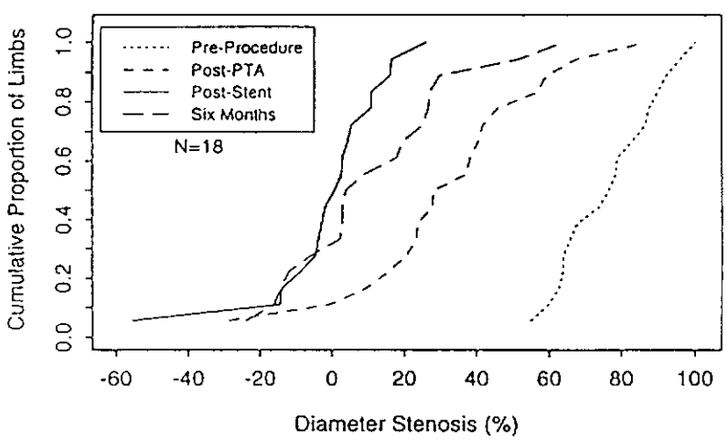

Figure 3. Baseline, Post-PTA, Post-Procedure, and Six Month Angiographic Percent Diameter Stenosis for Limbs with All Four Measurements - Core Lab

Tables 5 presents the effectiveness data. Percent stenosis is calculated by measuring the native vessel diameter at the most narrow point of the lesion divided by the estimated native vessel diameter, subtracted from one and times 100 for percent.

Note: The <50 percent residual stenosis criteria for Acute Procedure Success does not correlate with the criteria of a ≥ 30 percent residual stenosis for suboptimal angioplasty. Analysis of the data revealed that five patients treated with the WALLSTENT® Iliac Endoprosthesis had a residual stenosis of ≥ 30 percent but < 50 percent post-procedural.

Table 5 - Effectiveness Measures*
(Unit of Analysis is Limbs)

		%		95% CI
Acute Procedure Success	136/137	99.3		96.0-100
Acute Procedure Success (Core Lab)	111/112	99.1		95.1-100
30 Day Procedure SuccessΔ	129/137	94.2		90.3-98.1
30 Day Procedure Success (Core Lab)	104/112	92.9		88.1-97.1
Six Month Angiographic Success	59/65	91		84-98
Late Clinical Success	88/104	85		78-91
ABI - pre	n=120	0.65 ± 0.17		0.62 - 0.68
ABI - post	n=98	0.86 ± 0.20		0.82 - 0.90
ABI - 6 Month	n=85	0.87 ± 0.20		0.83 - 0.92
	One Year		Two Years	
Patency†	%	95%CI	%	95%CI
Primary	88	82-94	78	71-86
Primary Assisted	98	95-100	94	89-98
Secondary	98	95-100	94	89-98

* A total of 137 limbs in 119 patients.
† Life table analysis: value given is life table estimate and 95%CI.
‡ Mean ± SD
Δ Technical success + no major complications within 30 days of implant.

Table 6 - Rutherford/Becker Score Post-Procedure (≈42 days) Clinical Success			
Variable		**Frequency**	**%**
Rutherford/Becker Score (n=128 limbs)	+3	77	60.2
	+2	22	17.2
	+1	21	16.4
	0	8	6.3
	-1	0	0
	-2	0	0
	-3	0	0
Early Clinical Success[1] (n=128 limbs)		120	93.7

[1] Rutherford/Becker ≥ 1

Kaplan-Meier survival analysis with 95% confidence intervals for angiographic failure and clinical patency failure are presented in Figures 4 and 5, respectively.

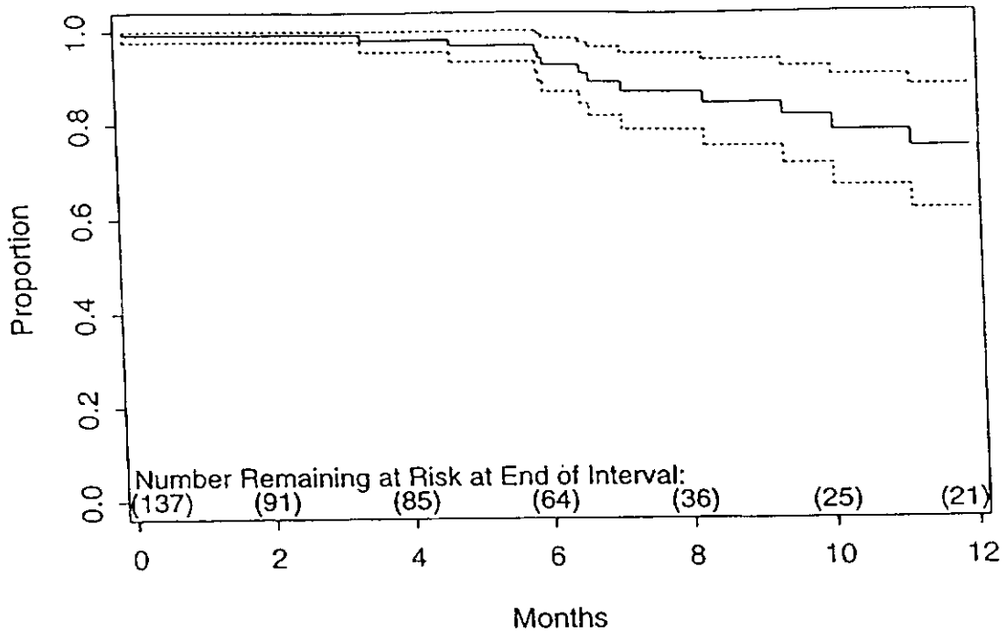

Figure 4. Time to Angiographic Failure - Kaplan-Meier Survival Analysis (with 95% CI)

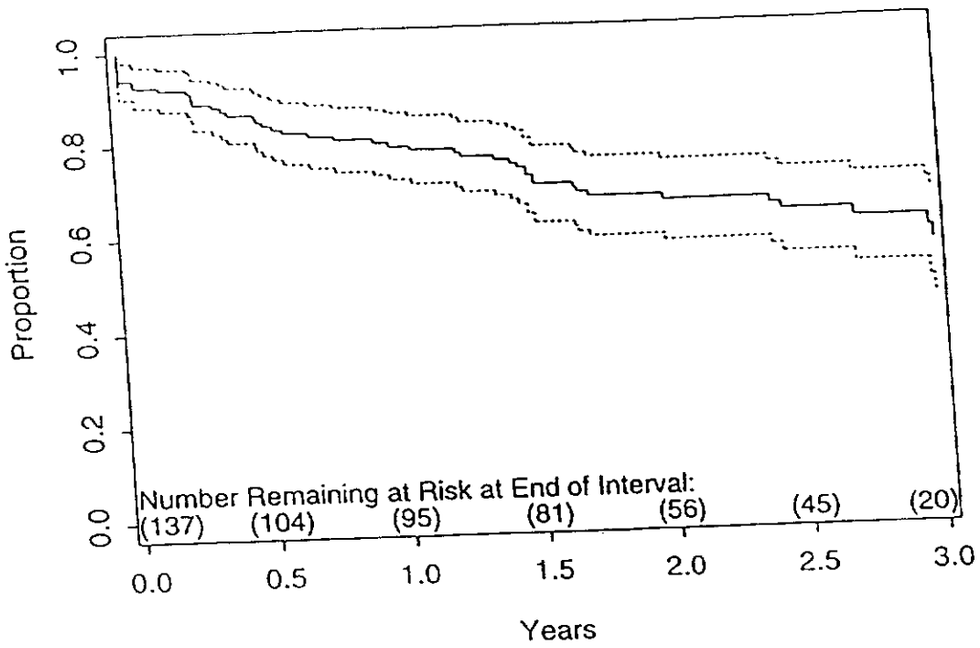

Figure 5. Time to Clinical Failure - Kaplan-Meier Survival Analysis (with 95% CI)

Figures 6 illustrate time to primary, primary assisted and secondary patency, respectively. These are Kaplan-Meier survival analysis with 95% confidence intervals. No statistical difference was detected between stents placed in the common or external iliac artery.

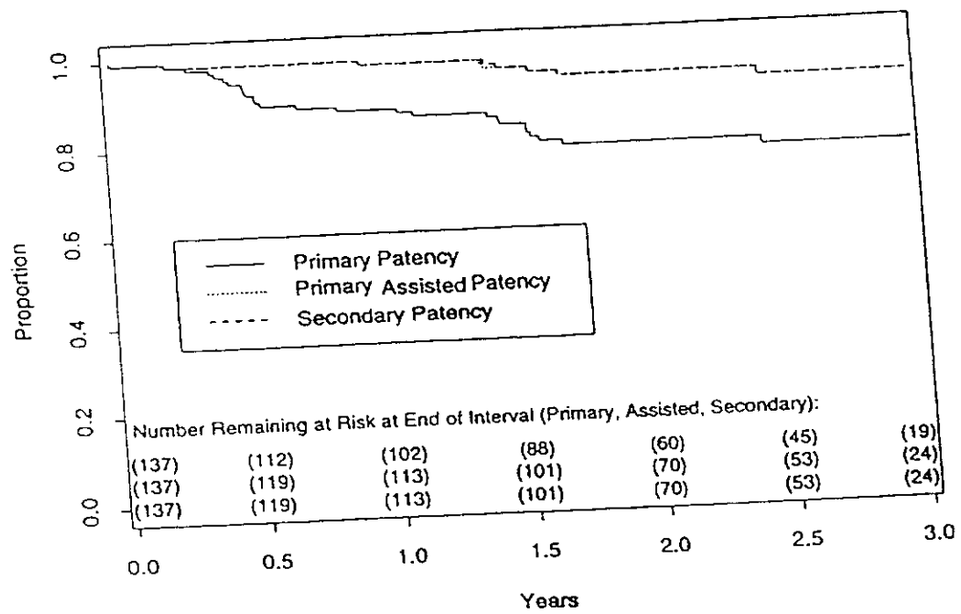

Figure 6. Time to Failure of Primary, Primary Assisted, and Secondary Patency - Kaplan-Meier Survival Analysis (with 95% CI)

Figures 7 and 8 illustrate the maintence of SVS clinical grade and ABI score over a two year period.

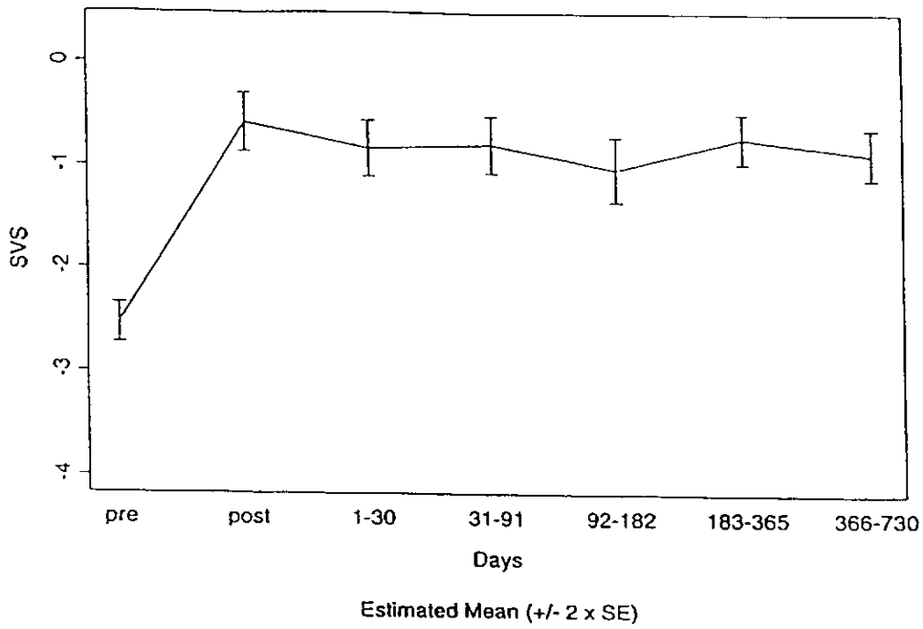

Figure 7. SVS Clinical Grade Maintence Over Time For Iliac Limbs

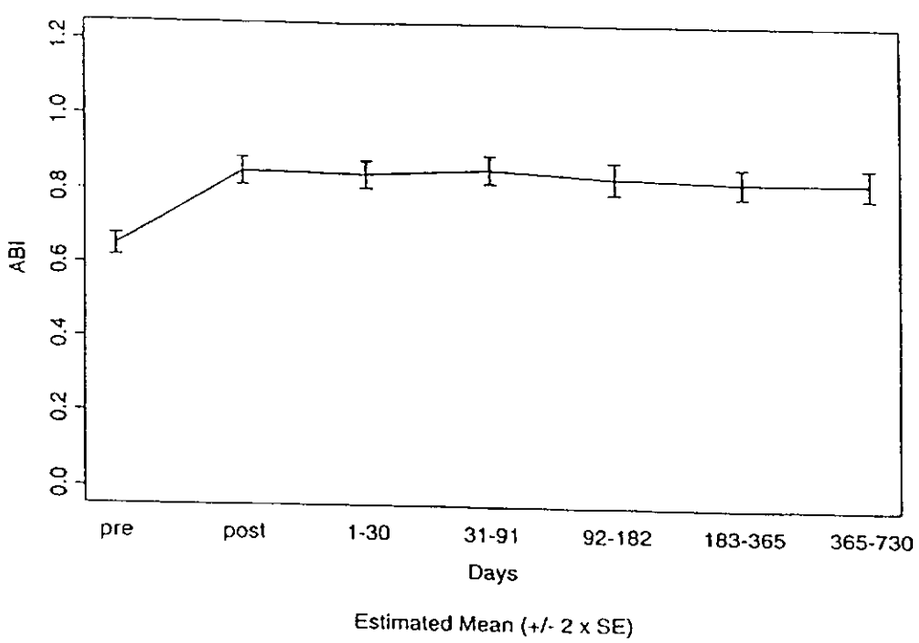

Figure 8. ABI Score Maintence Over Time For Iliac Limbs

Table 7 presents the safety data. The safety measures of major clinical events within 30 days includes the complications of death, stroke, bleeding requiring transfusion, or any complication which is device or procedure related and requires a surgical or interventional procedure.

Table 7 - Safety Measures
(Unit of Analysis is Patients, n=119)

Major Clinical Events ≤ 30 days	# Events	95% CI
In Hospital	5 (4.2%)	1.4 - 9.5
Out Hospital	1 (0.8%)	0 - 4.6
No Events	113 (95.0%)	89.3 - 98.1
All Events		
Early Death	3 (2.5%)	0.5 - 7.2
Late Death	12 (10.1%)	5.3 - 17.0
Early CVA	0 (0%)	0 - 3.1
Late CVA	2 (1.7%)	0.2 - 5.9
Bleeding Requiring Repair	1 (0.8%)	0 - 4.6
Hematoma Requiring Repair	1† (0.8%)	0 - 4.6
Pseudoaneurysm	1 (0.8%)	0 - 4.6
Distal Emboli	2 (1.7%)	0.2 - 5.9
Early Stent Thrombosis	0 (0%)	0 - 3.1
Late Stent Thrombosis	4 (3.4%)	0.9 - 8.4
Minor Hematoma	10 (8.4%)	3.4 - 13.4
Intraluminal Thrombus	2 (1.7%)	0.2 - 5.9

One additional patient developed a hematoma requiring repair following the six month angiogram.
Early is defined as > 30 days.
Late is defined as ≥ 30 days.

Table 8 presents data on the performance of the delivery system. It should be noted the failure to prime and hold pressure failure modes do not apply to the Unistep™ Delivery System but were associated with the early delivery system design termed "rolling membrane".

Table 8 - Delivery System Failures (n=165 stents)

	n	%	95% CI
Stent Misplacement	6	3.6	0.8-6.6
Failure to Prime	3	1.8	0-3.8

Comparison to Historical Control

The published summary of safety and effectiveness for the PALMAZ™ Balloon Expandable Stent (P890017, Johnson and Johnson Interventional Systems) serves as the principal source of historical data on the use of endovascular stenting after suboptimal PTA. This series was subsequently updated in a published journal article, and the data from this article was also used for comparison. The baseline characteristics for the patients in the WALLSTENT® Endoprosthesis study were in general similar to the patients in both the Palmaz summary and Palmaz update. For both efficacy and complications results, the WALLSTENT® Endoprosthesis study results are comparable to the Palmaz summary and Palmaz update.

Patient and lesion characteristics and outcome from the Palmaz summary and update were reported primarily in terms of percentages. These percentages were used in the following comparison to calculate number of patients and limbs with given characteristics and outcomes, based upon the actual numbers of patients and limbs reported. These calculated numbers were then used to perform statistical comparisons between the WALLSTENT® data and the historical control groups.

Patient Population

Baseline patient characteristics for the WALLSTENT® Endoprosthesis study, and the two Palmaz references are presented in Table 9.

All studies were multicenter trials at major interventional centers. The groups were closely matched with respect to age, having mean patient ages between 61 and 64 years ($p=0.57$ versus Palmaz update). The WALLSTENT® group had a higher proportion of females (33% versus 20 and 25%); and this difference was statistically significant ($p=0.009$ versus Palmaz summary, and $p=0.081$ versus Palmaz, 1992).

A significant difference was identified for the proportion of the study population with a history of smoking ($p<0.001$), with fewer WALLSTENT® patients having smoking as a risk factor. Information collected in the WALLSTENT® trial relied upon patient responses, and did not solicit information from the patient's family or referring physician. For this reason, the true proportion of "smokers" in the sample may be underestimated.

The WALLSTENT® study had a somewhat higher proportion of diabetics than either the Palmaz summary ($p=0.056$), or the Palmaz update ($p=0.010$) studies. Diabetics are generally poorer risk patients, and were associated with less favorable clinical results in the 1992 Palmaz update. Univariate analysis of the clinical results in the WALLSTENT study determined that the diabetic patient had a significantly increased risk of failing clinical patency ($p=0.036$). There was no difference in the proportion of patients with coronary artery disease between the WALLSTENT® trial and the Palmaz study ($p=0.73$ and $p=0.57$ for Palmaz summary and Palmaz update, respectively).

The studies were very evenly matched with respect to the proportion of hypertensive patients (57% for WALLSTENTS® versus 52% for PALMAZ™ stents, $p=0.37$ and $p=0.32$ for Palmaz summary and Palmaz update, respectively). There was a significantly higher proportion of patients with claudication in the WALLSTENT® trial compared to the Palmaz update ($p=0.029$); the comparison to the Palmaz summary group was not significant ($p=0.15$).

Table 9 - Comparison of Baseline Data for Iliac Stented Lesions			
Variable	**WALLSTENT® Endoprosthesis**	**Palmaz Summary of Safety and Effectiveness**	**Palmaz et al 1992**
Number of:			
Patients	119	202	486
Limbs	137	225	567
Demographics:			
Age (mean)	63.5 ± 11	61.3	62.9 ± 10
Range	38-85	40-89	NR
Males	80/119 (67%)	80%	75%
Females	39/119 (33%)	20%	25%
Atherosclerosis Risk:			
Cigarette Smoking	71/119 (60%)	96%	94%
Diabetes	36/119 (30%)	21%	23%
Hypertension	68/119 (57%)	52%	52%
CAD	56/119 (47%)	45%	50%
Claudication	93/119 (78%)	71%	68%

NR = Not Reported

Pre-treatment Lesion Characteristics

Significant lesion characteristics have been summarized and are presented in Table 10. Mean lesion lengths were comparable between the WALLSTENT® and 1992 PALMAZ™ stent groups (3.0 ± 2.9 cm for WALLSTENTS® and 3.2 ± 3.1 cm for PALMAZ™, p=0.49). Fewer WALLSTENTS® were required (1.2/lesion versus 1.9/lesion), however, this was anticipated because the length of the WALLSTENT® is greater than that of the PALMAZ™ stent.

The mean percent stenosis for WALLSTENT® treated lesions was 70%, 76% for the Palmaz summary of safety and effectiveness, and 79% in the Palmaz 1992 update. A significantly higher percentage (26% versus 10.2%, $p<0.001$) of the Palmaz patients were returning due to restenosis in previously ballooned lesions.

Table 10 - Comparison of Pre-treatment Characteristics for Iliac Lesions			
Variable	**WALLSTENT® Endoprosthesis**	**Palmaz Summary of Safety and Effectiveness**	**Palmaz et al 1992**
Lesion Length (cm)	3.0 ± 2.5	NR	3.2 ± 3.1
Mean Stents/Lesion	1.2	1.4	1.9
Pre-procedure % Stenosis (mean)	70%	76%[1]	79%[1]
Restenosis of Previous PTA	14/137 (10.2%)	26%	NR
Calcified Lesions	73/134 (54%)	34%	NR

[1] Original reports included total occlusions, percents have been adjusted to represent only stenotic lesions.

Procedural Success

Success of vascular interventional procedures is most often evaluated on the basis of clinical and angiographic results. Comparison of study patients for initial and follow-up angiographic and clinical success is provided in Table 11.

Initial angiographic success was defined as a 50% or greater increase in lumen diameter following stent placement. Both stents provided excellent initial angiographic results, with 99% and 98% success for the WALLSTENT® and Palmaz stents respectively. Differences between the two groups were not statistically significant (p=0.65). The absolute change in vessel diameter was smaller for the WALLSTENT® group.

The follow-up angiographic success rate was 91% for the WALLSTENT® Endoprosthesis, and 93% for the Palmaz summary of safety and effectiveness (p=0.75).

In summary, initial and follow-up angiographic success obtained using the WALLSTENT® Endoprosthesis are comparable to those obtained using PALMAZ™ stents.

Clinical success was evaluated using two different criteria for the WALLSTENT® and Palmaz trials (SVS and Fontaine respectively). The SVS scale utilizes three categories to describe levels of claudication, versus two for the Fontaine scale. In spite of this difference, both studies defined success as an improvement of one clinical grade, and the results obtained should be comparable. In addition, the current trial, and the 1992 Palmaz update evaluated patients on the basis of Rutherford's criteria. Both studies defined success as a Rutherford classification of greater than zero.
Using the SVS criteria, 91% of the WALLSTENT® patients were classified as initial clinical successes. This compares to 85% initial success reported in the Palmaz summary of safety and effectiveness. This difference is not statistically significant (p=0.078). On the basis of the Rutherford classification scheme, 94% of the WALLSTENT® patients were successes, versus 99% for the Palmaz 1992 update group (p=0.002). Long term clinical success was comparable between the two stent groups (91% success for WALLSTENTS®, 89% success for Palmaz summary patients with a clinical grade improvement, p=0.69), and 76% for Palmaz summary patients with a hemodynamic improvement (p=0.008).

Table 11 - Initial and Follow-up Success Criteria

Variable	WALLSTENT® Endoprosthesis	Palmaz Summary of Safety and Effectiveness	Palmaz et al 1992
Initial Angiographic Success: Percent Successful Mean Pre-diameter Mean Change	 136/137 (99%) 2.5 mm 4.8 mm	 221/225 (98%) 2.5 mm 6.0 mm	 NR NR NR
Six Month Follow-up Angiographic Success: Percent Successful (limbs) Mean Follow-up Percent of Eligible Patients	 59/65 (91%) 7.2 Months 57/109 (52%)	 93% 7.8 Months 41%	 NR NR NR
Initial Clinical Success: Percent Successful Percent Rutherford >0 Long Term Success (up to one year)	 125/137 (91%) 129/137 (94%) 80/88 (91%)[1]	 85% NR 89%[2] (76%[3])	 NR 99% NR

[1] Rutherford/Becker >0.
[2] At least one level improvement in clinical status.
[3] At least 0.1 increase in ABI.
NR = Not Reported

Complications

Death is most often divided into: (1) early (≤30 days) or late, and (2) device related or not related. Neither the Palmaz trial nor the WALLSTENT® trial resulted in any device related deaths. The early mortality rate was not significantly different between this study and the Palmaz update (p=0.71), and is at the expected level for the severely compromised patients treated with these devices.

Three complications classified as "major" were encountered during the WALLSTENT® trial: hematomas requiring surgery or transfusion, pseudoaneurysm, and distal emboli formation. These complications are anticipated sequelae to any percutaneous vascular interventional procedure, and were also encountered during the Palmaz trials. The rates of each complication were low in all trials, and no statistically significant differences between study results were identified. Hematomas requiring intervention occurred in 0.8% of the WALLSTENT® patients and 4.0% of the Palmaz summary group (p=0.16). Pseudoaneurysms developed in one (0.8%) WALLSTENT® patients, and four (0.8%) Palmaz update patients (p=1.00). Finally, distal embolization was diagnosed in two WALLSTENT® patients (1.7%), four (2.0%) Palmaz summary patients (p=1.00), and six (1.2%) Palmaz update patients (p=0.66). There were no cases of acute thrombosis in the WALLSTENT® patients. Within the Palmaz summary and update, 0.5% (p=1.00) and 1.0% (p=0.59), respectively, reported acute thrombosis. These results are tabulated in Table 12.

Table 12 - Patient Mortality and Primary Complications

Variable	WALLSTENT® Endoprosthesis	Palmaz Summary of Safety and Effectiveness	Palmaz et al 1992
Patient Death:			
Death ≤30 Days	3/119 (2.5%)	NR	1.9%
Death >30 Days[1]	12/119 (10.1%)	NR	6.2%
Major Complications:			
Hematomas requiring surgery or transfusions	1/119 (0.8%)	4.0%	NR
Pseudoaneurysm	1/119 (0.8%)	NR	0.8%
Distal Emboli	2/119 (1.7%)	2.0%	1.2%
Acute Thrombosis	0/119 (0.0%)	0.5%	1.0%

[1] The length of follow-up between the WALLSTENT® study and Palmaz et al varied, therefore the rates are not comparable.

NR = Not Reported

XI. Conclusions Drawn From Studies

The nonclinical studies indicate the WALLSTENT® Iliac Endoprosthesis has the appropriate physical and performance characteristics for its intended use, as stated in the labeling. The biocompatibility tests and supporting data demonstrate the materials used in the delivery system are biocompatible for short term blood contact and the stent itself is acceptable for long term implant.

The multicenter clinical study showed that the WALLSTENT® Endoprosthesis had a technical and acute procedure success rate of 99.3%, and a 30 day procedure success of 94.2%. Comparison of safety and effectiveness data between the WALLSTENT® Endoprosthesis and the Palmaz Stent demonstrated comparable results for initial treatment success, and long term clinical and angiographic success, patient mortality, and major complications.

Using Kaplan-Meier survival analysis the primary, primary assisted and secondary patency rates at one year were 88% (95% CI = 82-94%), 98% (95% CI = 95-100%) and 98% (95% CI = 95-100%), respectively. Ninety-five percent of the patients experience no major complications. Five percent of the patients developed a major complication within 30 days of the procedure.

In conclusion, the nonclinical and clinical studies demonstrated with reasonable assurance that the WALLSTENT® Iliac Endoprosthesis is safe and effective when used according to the labeling for use following suboptimal angioplasty of the common and/or external iliac artery stenosis or occlusion.

XII. FDA Decision

On March 4, 1996, the results of the WALLSTENT® Iliac Endoprosthesis clinical investigation were presented to the Circulatory System Devices Panel. The panel recommended approval of the application with the following conditions: (1) review the angiograms to determine the patency status of the branch arteries crossed as a result of the WALLSTENT® Iliac Endoprosthesis implant and determine if additional instructions to the labeling is necessary; (2) revise the labeling to remove total iliac artery occlusions, anastomatic graft lesions, and concomitant hepatic insufficiency, nephrotic syndrome, thrombophlebitis, uremia or patients requiring dialysis or immunosuppressant therapy from the contraindications section; (3) revise the precaution section to include a statement that the safety and efficacy for total non-thrombotic iliac artery occlusions have not been demonstrated; (4) revise the precaution section to include a statement that the safety and efficacy for treatment of anastomatic graft lesions have not been demonstrated; and (5) revise the labeling to further clarify the measures of primary patency, primary assisted patency and secondary patency measures and specify that these measures do not reflect angiographic patency.

On April 17, 1996, Schneider (USA), Incorporated submitted an amendment to the application responding to recommendations by the panel and requested by FDA. The information contained in this amendment was found to be adequate and FDA issued an approval order to Schneider (USA), Incorporated on MAY 28 1996. Based on the information provided regarding branch arteries that were crossed with the implant of the device, it was determined that the labeling required no additional instruction. This approval is subject to the applicant's compliance with the conditions that the sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

FDA inspection of Schneider (USA), Incorporated's manufacturing facility determined it was in compliance with the Device Good Manufacturing Practices Regulation (21 CFR part 820).

XIII. Approval Specifications

In accordance with the 1990 Safe Medical Devices Act, Schneider (USA), Incorporated will be required to track the device because it is a permanent implant whose failure would be reasonably likely to have serious adverse consequences.

WALLSTENT® ILIAC
ENDOPROSTHESIS with UNISTEP™ DELIVERY SYSTEM

Schneider (USA) Inc • Pfizer Hospital Products Group • 5905 Nathan Lane North • Plymouth, MN 55442 U.S.A. • Tel 612-550-5500 • 1-800-822-1822 • Fax 1-800-325-9106

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician trained in interventional techniques and placement of intravascular stents.

PACKAGE INSERT
LA0173-001 DRAFT

DESCRIPTION
The Schneider WALLSTENT® Iliac Endoprosthesis is comprised of two components: the implantable metallic stent and the 7 Fr Unistep™ delivery system. The stent is composed of biomedical superalloy wire, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant and self-expanding. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during deployment. Radiopaque marker bands situated adjacent to the leading and trailing ends of the stent facilitate imaging during deployment. The interior tube of the coaxial system contains a central lumen which will accommodate a 0.035" or 0.038" guidewire. The device may be inserted through an 8 French introducer.

INDICATIONS
The Schneider WALLSTENT® Iliac Endoprosthesis is indicated for use following suboptimal percutaneous transluminal angioplasty (PTA) of common and/or external iliac artery stenotic lesions, which are ≤ 10 cm in length. A suboptimal PTA is defined as a technically successful dilation, judged by the physician to be suboptimal due to the presence of unfavorable lesion morphology such as:

- An inadequate angiographic and/or hemodynamic result as defined by a 30% or greater residual stenosis after PTA, lesion recoil, or intimal flaps.
- Flow limiting dissections post PTA longer than the initial lesion length.
- A 5mmHg or greater mean transtenotic pressure gradient post PTA.

CONTRAINDICATIONS
The WALLSTENT® Iliac Endoprosthesis is contraindicated for use in:

- Patients who exhibit persistent acute intraluminal thrombus at the proposed stenting site, post thrombolytic therapy.
- Patients who experience the complication of arterial perforation, or a fusiform or sacciform aneurysm during the procedure preceding possible stent implantation.

WARNINGS
- Care should be taken during stent deployment to avoid stent placement beyond the iliac ostium into the aorta as this may result in thrombus formation.
- Stents cannot be repositioned or removed after total deployment.

PRECAUTIONS
- Stenting across a major bifurcation may result in stenosis or occlusion of the non-stented vascular limb, and prevent or hinder future access for angioplasty procedures.
- The device is intended for use by physicians who have received appropriate training in interventional techniques and placement of intravascular stents.
- The WALLSTENT® Iliac Endoprosthesis may cause minimal artifacts in MRI scans due to distortion of the magnetic field.
- The WALLSTENT® Iliac Endoprosthesis is intended for single use only. The sterile packaging and device should be inspected prior to use. If it is suspected that sterility or performance of the device has been compromised, the device should not be used.
- The WALLSTENT® Iliac Endoprosthesis should NOT be resterilized.
- The safety and effectiveness of the WALLSTENT® Iliac Endoprosthesis for use in total nonthrombotic iliac artery occlusions has not been established.
- The safety and effectiveness of the WALLSTENT® Iliac Endoprosthesis in patients for whom antiplatelet, anticoagulation therapy, or thrombolytic drugs are contraindicated or who exhibit coagulopathy has not been established.
- The safety and effectiveness of the WALLSTENT® Iliac Endoprosthesis for use in pediatric patients has not been established.
- The safety and effectiveness of the WALLSTENT® Iliac Endoprosthesis for use at a lesion site within a vascular graft or at the anastomosis has not been established.

ADVERSE EVENTS
The clinical study of the WALLSTENT® Iliac Endoprosthesis included 119 patients receiving 165 stents at 13 US centers with a mean duration of 3.3 years and a range of 2 days to 4.3 years.

Fifteen patients died during the study. None of these deaths were believed to be device or procedure related.

The proportion of patients with adverse events (major and minor) reported in the 119 patients are listed below according to clinical importance.

Table 1 - Adverse Events (n=119)*

Event	<30 days	Total
Thrombosis	0%	3.4%
Stent Misplacement	3.6%	3.6%‡
Bleeding Requiring Transfusion	0.8%	0.8%
Hematoma Requiring Repair	0.8%	1.7%†
Distal Emboli	1.7%	1.7%
Pseudoaneurysm	0.8%	0.8%
Minor Hematoma	7.6%	8.4%†
Intraluminal Thrombus (subtotal)	0%	1.7%
Cerebrovascular Incident	0%	1.7%
Death	2.5%	12.6%

* Analysis on 119 of 140 patients in 137 limbs. Twenty-one patients excluded, 10 for not meeting study entry criteria & 11 were total occlusions.
‡ Aortic bifurcation involved 1.8%.
† One event occurred at follow-up angiography.

Additional adverse effects associated with iliac stenting, although not observed in the clinical study include:

- Vessel Rupture
- Sepsis/Infection
- AV Fistula Formation
- Stent Migration

The risks associated with the use of contrast media angiography (allergic type reactions, hypertension, shock, death), should also be considered, as fluoroscopy and angiography are recommended during the stent implant procedure.

CLINICAL SUMMARY

A prospective, multicenter, non-randomized, historically controlled trial was conducted to evaluate the WALLSTENT® Iliac Endoprosthesis when implanted following suboptimal PTA of common and/or external iliac artery stenosis. The results were compared to the historical control, a USA commercially available iliac stent. The study was performed at 13 US centers in 140 patients. Key patient demographic data for study patients are summarized in Table 1.

Primary safety and effectiveness measures were assessed as follows. Patients were evaluated clinically at the preop visit, discharge, 2 and 6 weeks, 3, 6, 9, and 12 month, and every 6 months thereafter. Symptoms were classified using Society of Vascular Surgery (SVS) clinical categories. Segmental blood pressures were measured from which ankle brachial (ABI) and thigh brachial (TBI) indices were calculated. Angiography was performed using standard intra-arterial angiographic techniques. Pre- angioplasty, pre- and post-stent, and 6 month films were submitted for quantitative core laboratory assessment.

The multicenter clinical study showed that the WALLSTENT® Iliac Endoprosthesis had a technical and acute procedure success rate of 99.3%, and a 30 day procedure success of 94.2%. Comparison of safety and effectiveness data between the WALLSTENT® Iliac Endoprosthesis and the historical control demonstrated comparable results for initial treatment success, and long term clinical and angiographic success, patient mortality, and major complications.

Table 2 - Demographics (n=119)*

Age (Yrs)†	63.5 ± 11.3 (38-85)
Gender	67% Male; 33% Female
Current/Recent Smoker	59.7%
SVS (n=121 limbs)†	2.56 ± 1.12 (0-6)
ABI (n=120 limbs)†	0.65 ± 0.17 (0.24-1.09)
NYHA (%)	I-70, II-23, III-7, IV-1
Diabetes	30.3%
Hypertension	57.1%
Hypercholesteremia	41.2%
Hyperlipidemia	26.9%
Myocardial Infarction	33.6%
Angina	29.4%
CHF	8.4%
Stroke	5.9%
TIA	3.4%
COPD	10.9%

* Analysis on 119 of 140 patients in 137 limbs. Twenty-one patients excluded, 10 for not meeting study entry criteria & 11 were total occlusions.

† Mean ± SD, (range).

Table 3 presents baseline lesion characteristics. Table 4 presents the effectiveness data. Acute procedure success is limbs exhibiting <50% stenosis immediately after stent placement and no major complications within the lab. Percent stenosis is calculated by measuring the native vessel diameter at the most narrow point of the lesion divided by the estimated native vessel diameter, subtracted from one and times 100 for percent.

Table 3 - Baseline Lesion Characteristics (Unit of Analysis is Limbs)

		Mean ± SD or %	Range Among Sites
Reference Vessel Diameter (mm) (n=137 limbs)		8.00 ± 1.37	6.5 - 8.65
Lesion Length (mm) (n=135 limbs)		30.30 ± 25.04	4.0 - 59.2*
Minimum Lumen Diameter (mm) (n=137 limbs)		2.46 ± 1.48	0.8 - 3.3
% Stenosis Pre-procedure (n=137 limbs)		69.6 ± 16.9	62.0 - 90.0
Location of Lesion (n=137 limbs)	Common	48.9%	0 - 100%
	External	51.1%	0 - 100%
Calcification Present (n=134 limbs)	No	45.5%	0 - 80%
	Yes	54.5%	
Eccentric Lesions (n=136 limbs)	No	34.6%	37.5 - 100%
	Yes	65.4%	

* Two patients had lesions >100mm prePTA but stent length <100mm and therefore were not excluded.

Table 4 - Effectiveness Measures* (Unit of Analysis is Limbs)

		%	95%CI
Acute Procedure Success	136/137	99.3	96.0-100
Acute Procedure Success (Core Lab)	111/112	99.1	95.1-100
% Stenosis Post Stent‡	n=137	8.0 ± 15.1	5.5-10.5
% Stenosis @ Six Months Angiography‡	n=65	12.1 ± 23.7	6.3-17.9
Six Month Angiographic Success	59/65	91	84-98
ABI - pre	n=120	0.65 ± 0.17	.62-.68
ABI - post	n=98	0.86 ± 0.20	.82-.90
ABI - 6 Month	n=85	0.87 ± 0.20	.83-.92

	One Year		Two Years	
Patency†	%	95%CI	%	95%CI
Primary	88	82-94	78	71-86
Primary Assisted	98	95-100	94	89-98
Secondary	98	95-100	94	89-98

* A total of 137 limbs in 119 patients.
† Life table analysis: value given is life table estimate and 95%CI.
‡ Mean ± SD

Figures 1 and 2 illustrate the Kaplan-Meier analysis for time to failure for primary, and primary assisted and secondary patency. Patency was not determined by longitudinal repeat angiography. These measures reflect the time to repeat intervention and are therefore dependent on patients returning for treatment. The dashed lines on the figures represent the upper and lower 95% confidence interval boundaries. Primary patency is defined as the time until first intervention; primary assisted as the time until total occlusion; and secondary as the time until the stented segment is bypassed or amputation of the extremity occurs due to restenosis or occlusion.

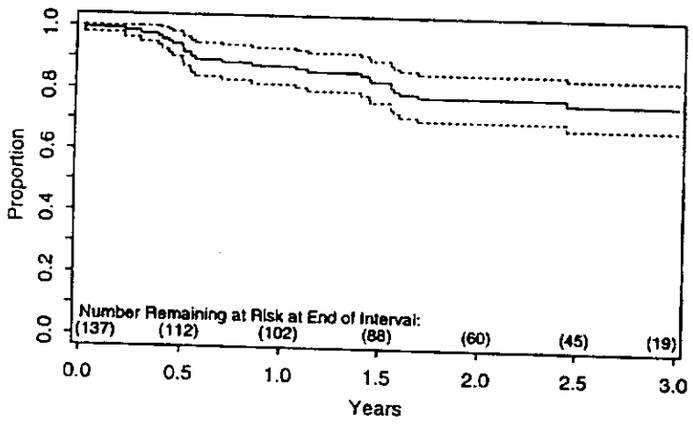

Figure 1. Time to Primary Patency Failure - Kaplan-Meier Survival Analysis (with 95% CI)

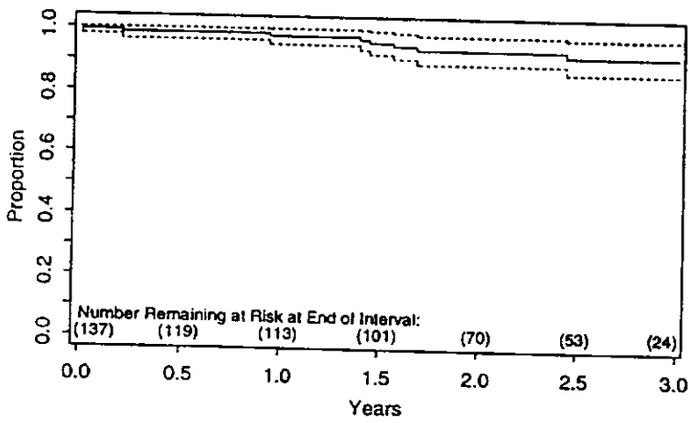

Figure 2. Time to Primary Assisted/Secondary Patency Failure - Kaplan-Meier Survival Analysis (with 95% CI)

Figures 4 and 5 illustrate the longitudinal (repeated measure) analysis of ABI and SVS improvement, respectively. The results illustrate improvement remains well above the initial levels through two years with minimal reduction over this same time period.

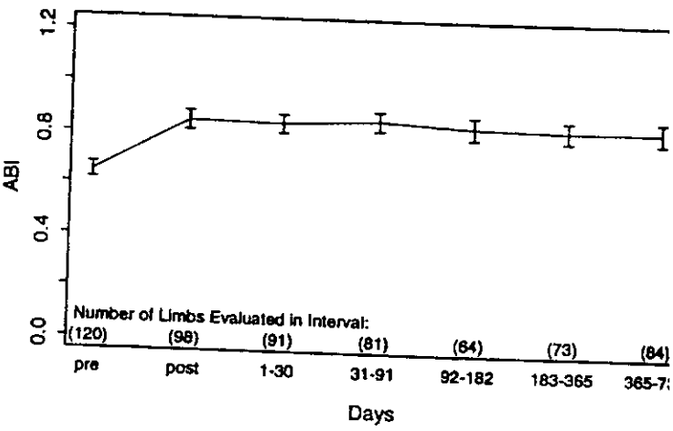

Figure 3. ABI Iliac Limbs (estimated mean +/- 2 x SE)

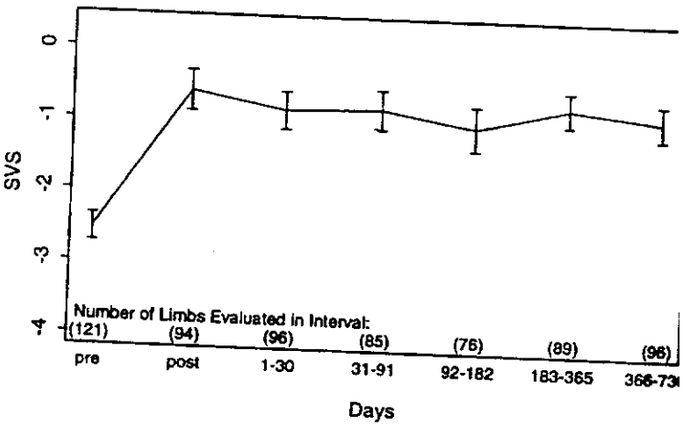

Figure 4. SVS Iliac Limbs (estimated mean +/- 2 x SE)

Table 5 presents the safety data. The safety measures of major clinical events within 30 days includes the complications of death, stroke, bleeding requiring transfusion, or any complication which is device or procedure related which requires a surgical or interventional procedure.

Table 5 - Safety Measures
(Unit of Analysis is Patients, n=119)

Major Clinical Events ≤ 30 days	# Events	95% CI
In Hospital	5 (4.2%)	1.4 - 9.5
Out Hospital	1 (0.8%)	0 - 4.6
No Events	113 (95.0%)	89.3 - 98.1
All Events		
Early* Death	3 (2.5%)	0.5 - 7.2
Late‖ Death	12 (10.1%)	5.3 - 17.0
Early* CVA	0 (0%)	0 - 3.1
Late∆ CVA	2 (1.7%)	0.2 - 5.9
Bleeding Requiring Repair	1 (0.8%)	0 - 4.6
Hematoma Requiring Repair	1† (0.8%)	0 - 4.6
Pseudoaneurysm	1 (0.8%)	0 - 4.6
Distal Emboli	2 (1.7%)	0.2 - 5.9
Early* Stent Thrombosis	0 (0%)	0 -3.1
Late∆ Stent Thrombosis	4 (3.4%)	0.9 - 8.4

* Early is defined as > 30 days.
‖ Late is defined as ≥ 30 days.
† One additional patient developed a hematoma requiring repair following the six month angiogram.

DIRECTIONS FOR USE

RECOMMENDED MATERIAL FOR IMPLANT

Prepare the following material using sterile technique:

- 10 cc syringe filled with sterile saline.
- 8FR hemostatic introducing sheath approximately 10-12cm long.
- 0.035 or 0.038" guidewire of appropriate length.

PRINCIPLES OF OPERATION

When sterile saline is injected between the interior and exterior tubes via the attached stopcock system, the delivery system becomes lubricated. Once lubricated, the exterior tube is easily retracted by moving the valve body towards the trailing end along the stainless steel tube. Retraction of the exterior tube permits the open end of the exterior tube to release the stent from constrainment. A single operator can thus control deployment and implant the stent (reference Figure A).

WARNINGS

- Care should be taken during stent deployment to avoid stent placement beyond the iliac ostium into the aorta as this may result in thrombus formation.
- Stents cannot be repositioned after total deployment.

PRECAUTIONS

- The device is intended for use by physicians who have received appropriate training in interventional radiological techniques, and placement of intravascular stents.
- The device is intended for single use only. The sterile packaging and device should be inspected prior to use. If it is suspected that sterility or performance of the device has been compromise, the device should not be used.

PREPARATION OF THE INSTRUMENT FOR INSERTION

1. Initial preparation of instrument

- Carefully remove the instrument from its protective packaging.
- Visually inspect the entire device for damage or defects.
- Visually check that the leading end of the stent is covered by the exterior tube.
- Ensure that no stent wires have perforated the exterior tube.

2. Priming the delivery system

- Attach a 10 cc syringe filled with sterile saline to the stopcock on the extension tube.
- Holding the device horizontally, open the stopcock and visually follow the advance of saline to the tip of the delivery system.
- After priming the delivery system, close the stopcock and remove the syringe.
- Reverify that the leading end of the stent is covered by the exterior tube. Do not use the device if the open end of the exterior tube has moved towards the trailing end, exposing the ends of the stent wires. Proper device function cannot be assured during implant and such use may cause vessel injury.

PROCEDURE

STENT LENGTH SELECTION

Calculate the vessel diameter and existing lesion length and allow for possible shortening of the stent, due to continued stent expansion post-implant. After considering the nominal, implanted diameter of the stent, select a stent that is longer than the minimum length so adequate lesion coverage is provided. (Refer to Table 6.) Should two stents be required to cover the lesion, place the distal stent first followed by the proximal stent, and allow for generous overlapping.

STENT PLACEMENT

1. Use the balloon dilation catheter radiopaque markers to identify the area to be dilated and stented.

2. Perform angioplasty using accepted technique and protocol, and use a 0.035" or 0.038" guidewire suitable for the exchange procedure.

3. Remove the balloon dilation catheter and check the lesion dimensions after angioplasty to ensure that the correct choice of stent has been made.

4. Having prepared the delivery system as described in "Preparation of the Instrument for Insertion", insert it over the guidewire and into the introducer sheath. An introducer sheath should always be used for the implant procedure. This will protect the puncture site if the need arises to withdraw a partially deployed stent.

5. Advance the stent across the site of the lesion, positioning the leading marker band slightly beyond the distal extremity of the dilated segment.

6. Guidelines for stent positioning:

- The leading and trailing markers should be aligned with the target vessel segment. These two markers define approximately the final position of the deployed stent.

- As the stent deploys, it shortens; therefore, care must be taken to maintain the leading and trailing markers over the segment to be stented.

- Maintain the delivery system as straight as possible during the deployment procedure.

CAUTION: A stent that is partially deployed too far distally can be pulled back slightly or removed from the patient provided that no more than half of the total stent length has been deployed (see step 8). A stent that is deployed too far proximally cannot be advanced distally.

7. Immobilize the stainless steel tube. While holding the hub with one hand, grasp the valve body with the other hand and gently slide the valve body along the stainless steel tube toward the hub until the stent is 50% deployed.

CAUTION: Do not push on the delivery system. The stainless steel tube must be immobilized securely. Pushing on the delivery system will cause misalignment of the stent and possible vessel damage. The stent should deploy easily. Do not release the stent if unusual force is required, since this may indicate a failed device. (See Step 10)

8. In the event a stent is partially deployed too far distal to the lesion site, the stent can be pulled back by first holding the valve body stationary and then pulling back on the stainless steel tube. Under fluoroscopy, the tip of the delivery system and the radiopaque marker will move proximally, through the lumen of the stent. The tip will stop when it becomes temporarily wedged in the unopened portion of the stent (see Figure B, step 3). Once the tip is locked in this position, secure the valve body and stainless steel tube concurrently and pull the device proximally to align the central length of the stent within the lesion.

CAUTION: Do not attempt to move the delivery system by pulling separately on either the valve body or stainless steel tube. Either action could inadvertently deploy the stent, resulting in misplacement.

9. Immobilize the stainless steel tube with one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube to complete stent deployment (see Figure B).

10. If a stent is partially deployed (≤50%) and too far proximal to the lesion site and removal of the stent is desired, the stent may be removed by holding the valve body stationary and pulling back on the stainless steel tube. This action, as previously described in step 8, wedges the tip in the unopened portion of the stent. Once the tip is wedged in place, secure the valve body and stainless steel tube concurrently and pull the entire device into the introducer sheath. The device and introducer sheath can then be removed, with the guidewire left in place.

11. After the stent is correctly positioned and fully deployed, the delivery system may be removed.

12. Using standard procedures, perform routine post implant angiography to demonstrate location and patency of the stent.

13. The implanted stent should allow for adequate overlapping of the lesion. In the event the stent does not cover the lesion, a second stent should be implanted providing adequate overlapping of the initial implanted stent.

If necessary, balloon dilation may be performed after stent implantation in order to obtain the maximum lumen diameter for the stent. The balloon catheter should be correctly sized to match the diameter of an adjacent normal segment of undiseased artery. To minimize the possibility of stent dislodgement, the use of a new balloon catheter is recommended.

DEVICE SIZES

The Schneider WALLSTENT® Iliac Endoprosthesis is available in the following dimensions. Stent diameter selected should be approximately 1mm larger than the vessel diameter desired. Deployed lengths reflect expansion to nominal stent diameter. Constricting the stent to a smaller diameter will cause a longer deployed length, depending on the degree of constriction. On average a 0.5 mm change in diameter yields a 10-15% change in length. Once the labeled diameter is reached no additional reduction in stent length should occur.

Table 6 - Stent Lumen Diameter and Approximate Implant Length (mm)

Model Number	Nominal Stent Lumen Diameter					
	5.0	6.0	7.0	8.0	9.0	10.0
S627110	37	28				
S637110	55	41				
S647110	73	55				
S667110	92	69				
S727110		34	25			
S737110		51	37			
S747110		85	62			
S767110		102	75			
S827110			32	23		
S837110			64	47		
S847110			80	58		
S867110			112	81		
S927110				30	22	
S937110				60	43	
S947110				89	65	
S967110				104	76	
S1027110					31	23
S1037110					61	46
S1047110					76	58
S1067110					107	81

NOTES
The Schneider WALLSTENT® Iliac Endoprosthesis is returnable only with prior Schneider authorization, and only in unopened shelf packs with all seals intact.

Schneider reserves the right to change or discontinue products without notice.

DISCLAIMER OF WARRANTIES

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FIGURE A

UNISTEP™ DELIVERY SYSTEM

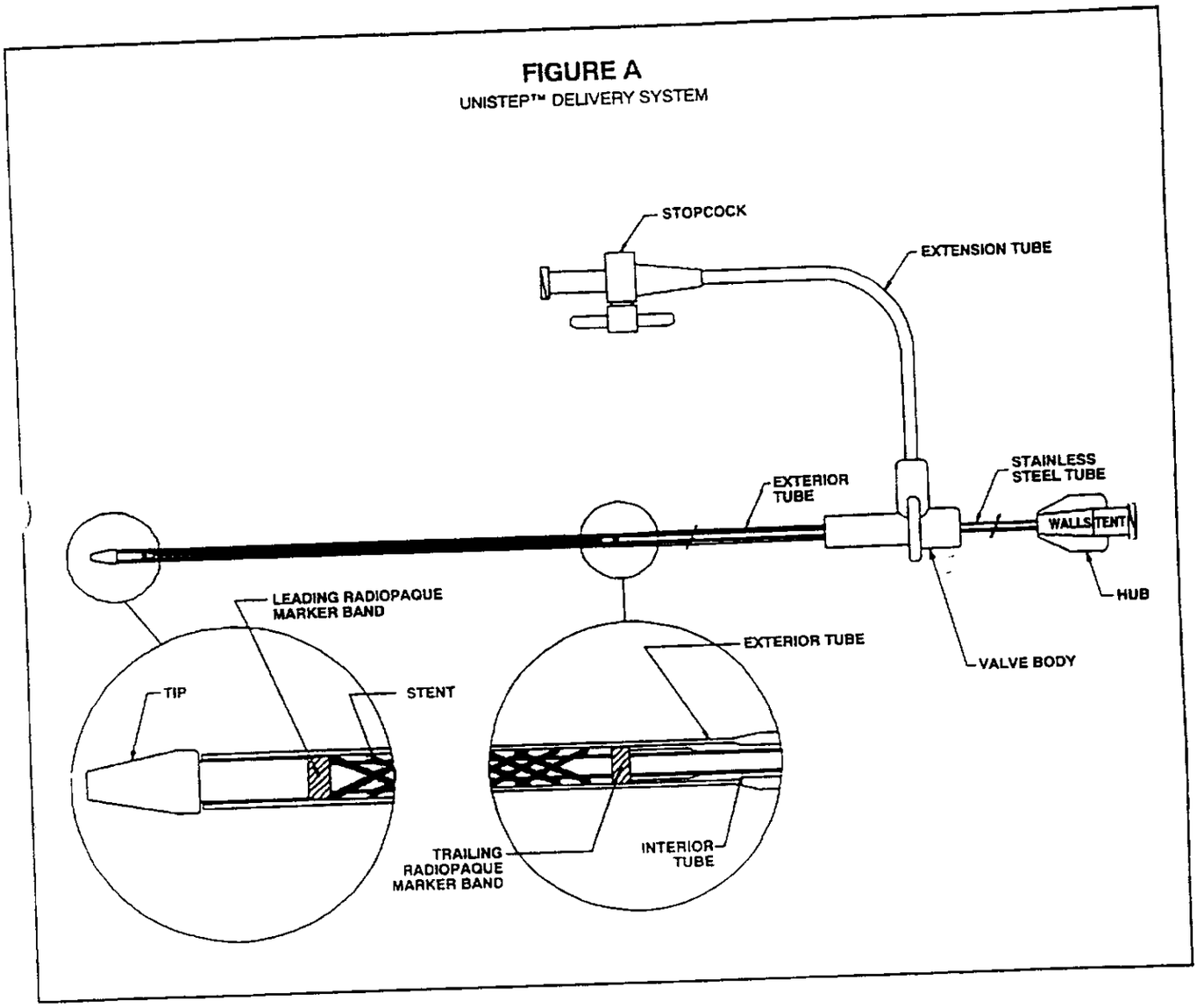
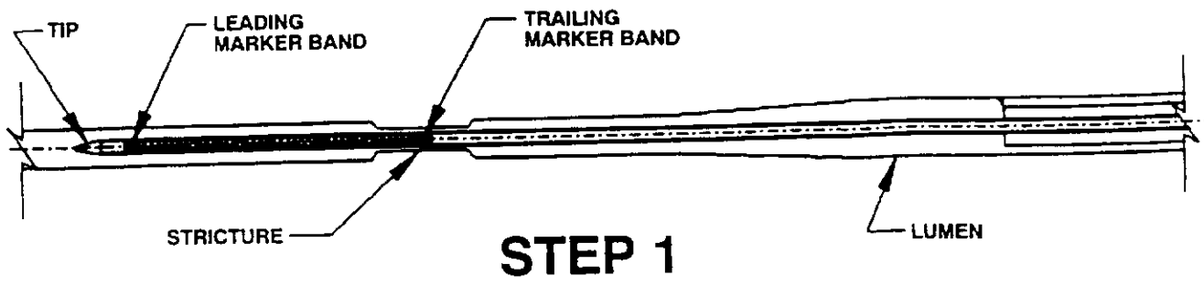
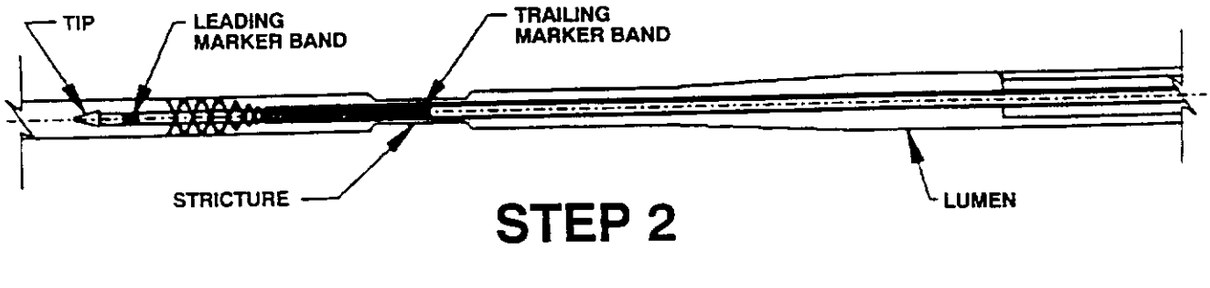


FIGURE B

UNISTEP™ DELIVERY SYSTEM

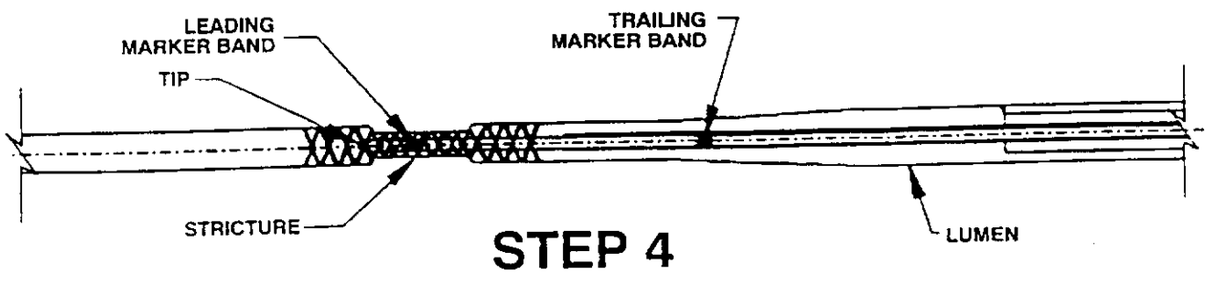


STEP 1



STEP 2

STEP 3



STEP 4